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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/27/2003

/o

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,856

Examiner

Cybille Delacroix-Muirheid

Applicant(s)

RADEMACHER ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/254,797.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Detailed Action

The following is responsive to Applicant's amendment received Jul. 7, 2003.

Claims 3 and 13 are cancelled without prejudice or disclaimer.

Claims 1, 2, 4-12 and 14-20 are currently pending.

The previous claim objection set forth in paragraph 1 of the office action mailed April 3, 2003 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, paragraph 2, set forth in paragraphs 2-3 of the office action mailed April 3, 2003 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The indicated allowability of claims 1, 2, 4-12, 14-20 is withdrawn in view of the following new ground of rejection.

Upon further consideration of the claims and prior art, the Examiner respectfully submits the following new ground(s) of rejection.

New Ground(s) of Rejection

Claim Rejections—35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 2, 4-12, 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a monoclonal antibody that binds to an A-type cyclitol containing carbohydrate substance comprising a Zn^{2+} ion. The claims fail to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1. There is insufficient descriptive support for the generic limitation "A-type cyclitol-containing carbohydrate substance comprising a Zn^{2+} ion", which may encompass any cyclitol-containing carbohydrate substance containing a Zn^{2+} ion. Furthermore, other than A-type IPG substances described in the specification (please page 16, lines 1-23; page 17, "Methods"; especially page 10, lines 32-33; page 9, lines 1-5; Figures 13-15) the claimed invention requires a monoclonal antibody that binds to any cyclitol-containing carbohydrate comprising a Zn^{2+} ion. In the absence of some understanding of additional structural characteristics of the claimed substance, one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed invention. The Examiner respectfully suggests amending the claims in such a manner as to describe the substance as an A-type IPG substance.

Claim Rejections—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5-7, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al.

Huang et al. disclose the invention substantially as claimed. Specifically, Huang et al. teach an inositol phosphoglycan antibody which blocks the effects of a pH 1.3 mediator isolated from liver. Huang et al. disclose that the pH 1.3 mediator contains myo-inositol and inhibits cAMP-dependent protein kinase. Huang et al. also disclose an « assay » method, where the antibody is pre-incubated with inositol phosphoglycan mediators and determining whether the antibody binds to the sample by observing that the mediators activities are completely inhibited. Please refer to the abstract; page 656, first column, lines 10-12.

The claims are anticipated by Huang et al. because Huang et al. disclose an antibody that binds to and antagonizes the effects inositol phosphoglycan substances isolated from liver, one of which inhibits cAMP-dependent protein kinase, i.e the pH 1.3 mediator.

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al., supra.

Huang et al. as applied above.

Huang et al. do not specifically disclose a pharmaceutical composition of the antibody and an acceptable carrier; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the antibody into a pharmaceutical composition because the disclosed antibodies have pharmacological activity, i.e. they block the effect of insulin, inhibit the action of purified insulin mediators

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in vitro etc., and such a modification would have been motivated by the reasonable expectation of effectively delivering the antibodies to a host in need thereof. Please see page 654, first column, first full paragraph.

Conclusion

Claims 1, 2, 4-12, 14-20 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CDM

Oct. 20, 2003



MARIANNE C. SEIDEL
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